

Docket No.: 29475/39204
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Timothy J. Taylor et al.

Application No.: 10/720,862

Confirmation No.: 5172

Filed: November 24, 2003

Art Unit: 1751

For: Antimicrobial Compositions Containing an
Aromatic Acid and a Hydric Solvent

Examiner: N. Ogden

DECLARATION OF EARL P. SEITZ UNDER 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

NOW COMES EARL P. SEITZ, Declarant herein, and states as follows:

1. I am a coinventor of the invention disclosed and claimed in the above-identified patent application.
2. I have been employed by The Dial Corporation (Dial), Scottsdale, Arizona, since 1978. I was a Research Manager of various technology and product development groups at Dial from 1980 to 1994. I am presently a Research Fellow at Dial, and have held this position since 1994. I am engaged in the research and development of personal care products, including compositions containing topically active components. In 2001, I was awarded Dial's R&D's highest technical award, the Robert E. Casely Award for Excellence in Innovation.
3. I received a Ph.D. in organic chemistry from Oregon State University, Corvallis, Oregon (1977), and a B.S. in chemistry from Texas Christian University, Fort Worth, Texas (1968). I also served in the U.S. Navy from 1969-1972, and held a post-doctoral position at The University of Wisconsin, Madison, WI in 1977 and 1978.

4. I have conducted research in the fields of skin cleansers and related surfactant-based compositions, including topically active and antibacterial compositions. I am a named inventor on seven U.S. patents involving technology disclosed in the above-identified patent application.

5. I have read and understand the Office Action dated March 28, 2008, which was issued in connection with U.S. Patent Application Serial No. 10/720,862. I also have read and understand the following patent cited by the examiner in U.S.S.N. 10/720,862: Beerse et al. U.S. Patent No. 6,294,186 ('186)).

6. Claims 2, 3, 5, 6, 9, and 11-26, all of the claims in the application, have been rejected as being obvious over the '186 patent. The basis of this rejection is that a skilled person would expect the claimed compositions to exhibit a similar antibacterial activity to compositions of the '186 patent because the '186 patent teaches the "same" ingredients. Contrary to the examiner's assertion, the compositions disclosed in the '186 patent are substantially different from the compositions recited in the presently-claimed methods.

7. The '186 patent describes and claims compositions comprising an antimicrobial agent. The title of the specification of the '186 patent is "Antimicrobial Compositions Comprising a Benzoic Acid Analogue and a Metal Salt". The '186 patent explicitly teaches that the metal salt contributes to the antimicrobial activity. For example, the '186 patent states that "[W]ithout being limited by theory, it is believed that the compositions of the present invention, the benzoic acid analog and metal salt complex to form a metal-acid complex which has been found to provide the synergistic immediate and residual anti-viral and anti-bacterial efficacy to surfaces to which such compositions are applied" ('186 patent, column 7, lines 60-65).

8. The '186 patent contains 42 examples. Of these 42 examples, 41 contain a metal salt as an antimicrobial agent in addition to the aromatic carboxylic acid.

9. The '186 patent also discloses a second embodiment wherein the composition contains a benzoic acid analog and a dermatologically effective carrier, and is essentially free of metal salts. This embodiment is identified by one sole example, namely

Example 21 in the '186 patent. However, the composition of this example also contains a total of 10 weight per cent of surfactants and 1.50% para-chloro-meta-xyleneol, which is a second antimicrobial agent.

10. With regard to a hydric solvent, the '186 patent recites that a carrier for the disclosed composition can be an alcohol (see for example, column 9, lines 33-54 of the '186 patent). The sole disclosure in the '186 patent of dipropylene glycol, as claimed in the present invention, is in Examples 16 to 18. In these examples, the amount of dipropylene glycol is 8% by weight. Examples 16 to 18 of the '186 patent also include a metal salt, which is excluded from the present claims.

11. As stated above, the presently claimed composition includes aromatic carboxylic acid as the *sole* antimicrobial agent, an amount of hydric solvent, and 0% to 0.2% by weight of a surfactant. Having read the '186 patent, I can find no disclosure or suggestion that would lead a person skilled in the art to the presently claimed composition.

12. Moreover, the '186 patent *explicitly* teaches that the metal salt is an essential ingredient in the first embodiment of the invention, and that the metal salt contributes to antimicrobial activity. In contrast to the '186 patent, the present claims exclude the presence of a metal salt that is taught as essential in the '186 patent.

13. In the second embodiment of the '186 patent, a metal salt is absent. However, the sole example of this embodiment, i.e., Example 21, differs in three substantial ways from the presently claimed composition. Firstly, although the composition of Example 21 is free of a metal salt as a second antimicrobial agent, the composition contains 1.50% by weight of the additional antimicrobial agent para-chloro-meta-xyleneol (PCMX), i.e., a phenolic antimicrobial agent. This antimicrobial agent is excluded from the claims of the patent application in suit, i.e., it is not an aromatic carboxylic acid.

14. Secondly, Example 21 in the '186 patent contains a high amount of surfactant (10 weight per cent). In contrast, the present claims recite a composition having 0% to 0.2% by weight of a surfactant. Thirdly, Example 21 of the '186 patent is free of a hydric solvent, which is required in the claims of the application.

15. In summary, it is my opinion that the '186 patent teaches that a metal salt is essential to provide a synergistic effect, as a second microbial agent together with a first aromatic antimicrobial agent. As a skilled person, when reading this document I am told that the metal salt is essential for performing the invention of the '186 patent. In view of the teaching of the '186 patent that the metal salt provides a synergistic effect, it would be my belief on reading this document that omitting the metal salt would cause the invention of the '186 patent to fail, i.e., not provide sufficient antimicrobial action. Further, if a metal salt is excluded, the '186 patent then teaches me that a different second antimicrobial agent, e.g., PCMX, must be present to be efficacious, as in Example 21 of the '186 patent.

16. However, the disclosure of the '186 patent is inconsistent and has one example in which the metal salt is omitted, despite the fact that the document appears to be geared toward compositions containing a metal salt. However, this embodiment is substantially different from the composition of the present claims and it is meaningless to compare Example 21 with the compositions of the invention, given that the example is so different from the claimed invention. Moreover, Example 21 also contains a further antimicrobial agent to provide an enhanced antimicrobial effect in view of the absence of a metal salt.

17. The efficacy of the present invention is demonstrated by the examples in the specification. Examples 1-3 show that pH is important to enhance efficacy (Ex. 1), that a hydric solvent alone is not efficacious (Ex. 2), and that an aromatic carboxylic alone, i.e., in the absence of a hydric solvent, is not efficacious.¹ Example 4 shows that a minimum amount of hydric solvent is required to achieve a log reduction of at least 3, as claimed. Example 9 shows that the method and composition are highly effective in reducing viral populations.

18. These efficacious results are achieved by using compositions free of a metal salt, essentially free of a surfactant, and containing an aromatic carboxylic acid as the sole antimicrobial agent in the composition. A person skilled in the art, after reading the '186 patent, would not have considered making any of these modifications, let alone all three, and still expect to provide a log reduction against *S. aureus* and/or *E. coli* of at least three.

¹ Efficacy is measured as a log reduction against *S. aureus* and/or *E. coli* of at least 3 after 30 seconds contact.

19. The compositions claimed in the present application require a sole antimicrobial agent and is essentially free of an optional surfactant. The inventors of the present application have determined using their inventive skill that an antimicrobial composition can be effective using a sole antimicrobial agent without the mandatory metal salt of the '186 patent (to provide synergistic activity) or a second antimicrobial agent. Despite not having *either of* these ingredients, the claimed compositions are surprisingly effective.

20. The use of a single antimicrobial agent in the present application is an advantage, not least in terms of the resulting commercial product and ease of production of the product.

21. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; further, these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or document or any patent resulting therefrom.

Dated: 24 JULY, 2008


Earl P. Seitz